REMARKS

CLAIM AMENDMENTS

Claims 8-9, 12-17 and 38-41 are pending. Claims 10-11 and 30-37 have been canceled. Claims 1-7 and 18-29 were previously withdrawn from consideration pursuant to a restriction requirement.

The proposed amendments are as follows:

(a) The cancellation without prejudice of claims 10-11 and 30-37; and

(b) The current amendment of claims 8-9, 12-17 and 38-41.

Upon entry of the proposed amendments, claims 8-9, 12-17 and 38-41 will be pending in the application. The pending independent claim will be claim 8.

The proposed amendments to claims 8-9, 12-17 and 38-41 are clarifying amendments. No new matter has been added. The amended claims are supported by the specification and by the claims as originally filed. Each is limited to the species eplerenone, rather than to the class of aldosterone receptor antagonists previously claimed.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)

The Office rejected Claims 8-9, 12-17 and 38-41 under 35 U.S.C. §103(a), asserting that Perez et al. establishes a prima facie case of obviousness, rendering the claims unpatentable. The rejection is respectfully traversed.

Applicants assert that the claims are patentable over Perez et al., U.S. Patent No. 6,410,524, (the '524 patent). The Office cites the Human Clinical Trial of col. 16, line 44 – col. 26, line 43 in its rejection of the instant claims. The inclusion criteria of this trial required patients to be on a regimen included ACE inhibitors and allowed for a loop diuretic as concomitant therapy. The study drug was spironolactone (also referred to as ALDACTONE™). The "health-related quality of life questionnaire" was the Health Related Quality of Life questionnaire (HRQOL), which is considered a general health status measurement device.

In the instant case, the human clinical trial used to support these claims is example 32, beginning on page 103 of the specification. This trial used eplerenone as the study drug. There was no concomitant drug requirement; that is, the patients studied were not required to take an ACE inhibitor, thereby expanding the patient population and providing further differences from those

receiving the combination therapy disclosed in the '524 patent. This trial was prospectively designed to use a disease-specific measurement, the Kansas City Cardiomyopathy Questionnaire. *J. Am. Coll. Cardiology*; 35: 1245-1255. This questionnaire quantifies symptoms, physical limitations, social functioning, patients' sense of self-efficacy and quality of life.

The Office indicates that one of ordinary skill in the art would have been motivated to use the applicants' known compounds to improve the quality of life in a heart patient with a reasonable degree of expected success.

Applicants respectfully disagree with the Office in this matter. The data in the '524 patent was collected from a patient population taking ACE inhibitors, forming the basis for the combination treatment claimed therein. However, in the instant case, no such limitation exists – patients may or may not take ACE inhibitors. Additionally, in the instant case, example 32 sets forth patients that must suffer from heart failure and an acute myocardial infarction to be offered the test article, eplerenone, which is then further studied using disease specific measurements as indicated above. In this case, the method of determining quality of life is relevant – there is a different drug therapy (eplerenone vs. spironolactone and ACE inhibitors) and a different patient population (patients with HF and AMI). In a patient population suffering from multiple ailments and a different course of drug therapy, success can hardly be expected. This expectation of a lack of success drove the need for a more precise, disease –specific measurement device, the KCCQ. Additional measurement devices are also used in this trial to assist in validating the conclusions of the KCCQ.

Accordingly, Applicants maintain claims 8-9, 12-17 and 38-41 are novel in light of Perez et al. The use of a different drug therapy to treat patients with a different clinical presentation should not be considered obvious over the '524 patent. Withdrawal of the rejection based on obviousness is respectfully requested.

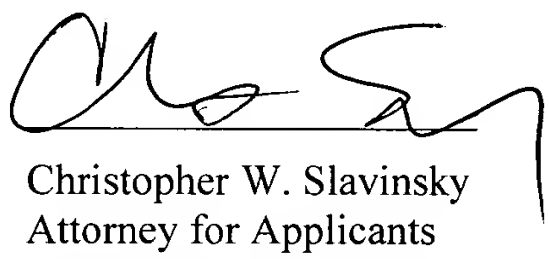
CONCLUSION

Applicants believe that the proposed amendments overcome all rejections and the claims are in condition for allowance. Thus, favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (314) 274-7008 at the Examiner's convenience.

It is believed that a three-month Extension of Time is required to render this paper timely filed. Applicants petition the Commissioner under 37 C.F.R. §1.126(a) for a three-month Extension of Time to respond to render the paper transmitted herewith timely. The Commissioner is hereby authorized to charge any appropriate fees for filing this Amendment and any necessary Extension of Time to Deposit Account 19-1025.

No excess claim fees are believed payable in respect of the present amendment. Further, if there is any other fee deficiency or overpayment of any fees in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or credit such overpayment to Deposit Account 19-1025.

Respectfully submitted:



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